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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,874	05/15/1998	PATRICIA A. BILLING-MEDEL	6106.US.P1	8815

23492 7590 01/13/2004

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/13/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/079,874

**Applicant(s)**

BILLING-MEDEL ET AL.

**Examiner**

Christopher H Yaen

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,23 and 31-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,23 and 31-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. RE: P.a. Billing-Medel *et al*, priority 5/15/1997

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/2003 has been entered.
3. Claims 1-21 and 24-30 are canceled without prejudice or disclaimer.
4. Claims 22-23, and 31-54 are pending and examined on the merits.

***New Arguments***

***Claim Objections***

5. Claim 36 is objected to because of the following informalities: the term "detectioin" is not a recognized word of which is not defined in the specification. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

6. Claims 22-23 and 31-54 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method of

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detection used for the claimed invention. It is unclear from the claims as to the type of detection method being employed. There are many different detection steps that are encompassed by the claims such as hybridization, column chromatography, in situ RT-PCR hybridization all of which fall within the scope of detection claimed. These steps are need for one of skill in the art to practice because conditions such as hybridization parameters, have not been provided so that one of skill could practice the invention without uncertainty.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 22-23 and 31-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following written description rejection is set forth herein.

The claims recite the detection of target polynucleotides using purified polynucleotides consisting of nucleic acid sequence selected from the group consisting of SEQ ID Nos: 1,4,5,8,and 10 as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential

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structural feature of all the possible target sequence that will be detected when using the said purified polynucleotides of SEQ ID No: 1,4,5,8,and 10. Because the claims as currently interpreted have not set forth conditions for said detection method nor has the claimed invention set forth any specific detection step, any sequence that would bind to said purified sequences by normal base pairing would be detected and as such would encompass an extensive number of sequences that are found within the test sample.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3<sup>rd</sup> column).

Applicant does not appear to have reduced to practice the detection of all target sequences that are capable of binding to the said purified sequence of SEQ ID No: 1,4,5,8 and 10 in a test sample. Neither has Applicant provided a sufficient written description of any structure that may be correlated with target sequence of urinary tract tissue gene UT116 that may be detected as a target sequence. A "target polynucleotide" sequence encompasses *any* nucleic acid sequence that is able to

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hybridize to any one of the purified SEQ ID numbers claims under any hybridization condition found within the test sample. Thus the genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed. In addition, as noted *supra* because the method steps have not been outlined, such as hybridization conditions, one of skill in the art would not be able to determine whether the applicant was in possession of all the possible target nucleotide sequence detected within the sample.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

9. Claims 31-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The following written description rejection is set forth herein

The claim as currently interpreted is drawn to a method of detecting the presence of a target polynucleotide in a test sample, wherein the method comprises contacting a test sample with at least one purified polynucleotide and detecting the presence of target in test sample with a purified polynucleotide. The claim recites the phrase "is selected from a group consisting of:", it is not clear to one of skill in the art that at the time of filing the applicant was indeed in possession of the claimed invention, because the polynucleotide encompassed are not described. Although it is clear that the group consists of SEQ ID Nos: 1, 4, 5, 8, and 10, applicant has not conveyed to one of skill in the art that the applicant was in possession of polynucleotides which read on any sequence found within SEQ ID Nos: 1,4,5,8, or 10 (because of the open interpretation of the word "is"). As such applicant has not provided adequate written description of the polynucleotide sequences found within or beyond those SEQ ID numbers. Examiner suggests that the applicant amend the claims to recite "the purified polynucleotide consisting of a nucleic acid sequence selected from the group consisting of".

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 37.**

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Mary B. Miloff for:*

Christopher Yaen  
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January 8, 2004